UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,424	07/29/2003	Frieder Braunschweig	P0010978.00	6026

27581   7590   03/17/2008
MEDTRONIC, INC.
710 MEDTRONIC PARKWAY NE
MINNEAPOLIS, MN 55432-9924

EXAMINER
PATEL, NATASHA

ART UNIT	PAPER NUMBER
3766	

MAIL DATE	DELIVERY MODE
03/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)
Office Action Summary	10/629,424	BRAUNSCHWEIG ET AL.
	Examiner	Art Unit	
	NATASHA N. PATEL	3766	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *1/22/08*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-5 and 7-12* is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-5 and 7-12* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on *29 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☐ All b)☐ Some * c)☐ None of:

      1. ☐ Certified copies of the priority documents have been received.

      2. ☐ Certified copies of the priority documents have been received in Application No. _____.

      3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.

4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

DETAILED ACTION

The RCE filed on 1/22/08 has been received and considered. By this RCE, Claims 1, 5, and 7 have been amended and Claims 6, 13, and 14 have been cancelled. Claims 1-5 and 7-12 are pending in the application.

Response to Arguments

Applicant's arguments filed on 1/22/08 have been fully considered but they are not persuasive. Applicant argues that neither Kieval nor Bornzin provides for delivery of a cardiac pacing therapy based on a lowest measured ePAD as measured when a patient is performing activities of daily living. However, the combination of Kieval and Bornzin does teach this. Kieval teaches the majority of the claim except for the collection of data during a patient's performance of daily living activities. Bornzin teaches the benefit of collecting data during patient activity to provide a more relevant therapy (see col. 2, lines 26-39). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use Bornzin's suggestion with Kieval's invention because applying a known technique (data collection during activity) to a known device ready for improvement (Kieval's optimization device) to yield predictable results (more appropriate pacing parameters for an active patient) shows obviousness.

Drawings

In view of Applicant's amendments to Figures 1-6 and 8, the examiner is withdrawing the objection that was made in the Final Rejection.

Claim Rejections - 35 USC § 112

In view of Applicant's amendment to Claim 5, the §112, first paragraph, rejection made

against Claims 5 and 7-12 in the Final Rejection have been withdrawn.

Claim Rejections - 35 USC § 103

1.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

2.   Claims 1-5, 7-8, and 11-12 are rejected under 35 U.S.C. 103(a) as being obvious

over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176).

3.   Regarding Claim 1, Kieval discloses a system for collecting hemodynamic data

from a patient (see col. 3, lines 42-44) and utilizing said data to optimize a cardiac

pacing regimen for said patient (see col. 4, lines 10-13), comprising: a means for

collecting hemodynamic data of a patient (see absolute pressure sensor 160 and

microcomputer 302; col. 3, lines 42-44) and for storing said collected hemodynamic

data (see RAM/ROM 310, 312, 314), wherein said hemodynamic data consists of a

lowest estimated pulmonary artery diastolic pressure (ePAD) value (see col. 11, lines 9-

18); a means for monitoring and/or stimulating cardiac tissue (see IPG 100) of a patient

to provide a desired cardiac rhythm and restore the desired cardiac rhythm (see col. 4,

lines 40-43), and a means for utilizing the collected lowest ePAD vaule with the means

for monitoring and/or stimulating cardiac tissue to optimize an atrio-ventricular (AV)

interval for said patient (see col. 12, lines 12-17 and col. 17, lines 34-54). The examiner

considers that although the hemodynamic data is stored in memory after it has already

been processed, the data is still being stored in some way, shape, or form. Furthermore,

the examiner considers that the hemodynamic data (RVP signal) is integrated into the

pulse generator's pacing program to establish an optimal AV delay (see col. 17, lines

25-29), which consequently optimizes a hemodynamic characteristic of the patient.

Although Kieval mentions activity levels (see col. 10, lines 41-42) and periods of rest

(see col. 10, line 64), Kieval does not explicitly disclose that hemodynamic data is

collected during both activity and rest. However, Bornzin discloses a similar optimization

system, in which the monitoring means (physiologic sensor 12) collects (see col. 7, lines

5-10) during periods of rest and periods when said patient is performing the activities of

daily living (see col. 8, lines 61-66). It would have been obvious to one of ordinary skill

in the art at the time of the invention to collect hemodynamic data during periods of rest

and during activity because Bornzin teaches the benefit of being able to differentiate

between activity and rest in order to provide an appropriate therapy (see col. 2, lines 26-

39).

4.   Regarding Claim 2, Kieval discloses that the lowest ePAD value is collected

using an absolute pressure sensor (see col. 8, lines 19-21) adapted to be fluidly coupled

to a cardiac chamber of the patient (see Figure 4). The examiner considers that sensor

160 on lead 114 has the ability to be fluidly coupled. Furthermore, it has been held that

the recitation that an element is "adapted to" perform function in not a positive limitation

in any patentable sense (*In re Hutchinson*, 60 USPQ 138).

5.   Regarding Claim 3, Kieval discloses that the means for monitoring and/or stimulating comprises a pulse generator (see col. 7, lines 54-55 and Figure 4).

6.   Regarding Claim 5, Kieval discloses a method of optimizing hemodynamics of a patient (see col. 4, lines 10-13) having an implantable cardiac rhythm stimulation and monitoring device (see IPG circuit 300), comprising the steps of: collecting hemodynamic data from said patient (see col. 3, lines 42-44) with a hemodynamic monitor (see absolute pressure sensor 160 and microcomputer 302) adapted to be disposed in fluid contact with a volume of venous blood of said patient (see col. 5, lines 59-61), wherein the hemodynamic data consists of the lowest ePAD value (see col. 14, line 64-col. 15, line 10); storing said lowest ePAD value in a computer readable medium (see col. 13, lines 21-28). The examiner considers since the pressure sensor 160 is in the right ventricle and the venous blood enters the right ventricle, then the pressure sensor 160 is in fluid contact with the venous blood. Kieval discloses storing said collected hemodynamic data (see RAM/ROM 310, 312, 314). The examiner considers that although the hemodynamic data is stored in memory after it has already been processed, the data is still being stored in some way, shape, or form. Kieval further discloses collecting cardiac event data from the patient (see col. 15, lines 40-46 and Figures 5 and 10) and storing the cardiac event data in a computer readable memory medium (see RAM/ROM 310, 312, 314). The examiner considers that although the ECG is stored in memory after it has already been processed, the ECG is still being stored in some way, shape, or form. Kieval discloses analyzing said lowest ePAD value in conjunction with said cardiac event data to determine an AV delay interval that

optimizes the hemodynamics of said patient, and providing said AV delay interval to an implantable cardiac rhythm stimulation device (see Kieval, col. 17, lines 34-54) as an operating AV delay interval for chronic delivery of cardiac pacing therapy. The examiner considers that since the AV delay is continually updated, then the heart will be paced to reflect those changes chronically. Kieval does not disclose collecting hemodynamic data during activity levels above resting rate. Bornzin discloses performing this collection process during a period of time when a heart rate of the patient is elevated above a resting rate due to activity by said patient (see col. 9, lines 9-15 and col. 6, lines 6-14). The examiner considers the heart rate will inherently be higher during physical activity compared to the heart rate during rest. It would have been obvious to one of ordinary skill in the art at the time of the invention to collect hemodynamic data during periods activity because a patient will not always be at rest and Bornzin teaches the benefit of being able to provide an appropriate therapy at any activity level (see col. 5, lines 26-30).

7.   Regarding Claim 7, Kieval discloses that the lowest ePAD value is collected substantially continuously (see col. 16, lines 19-23). The examiner considers since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed continuously, hemodynamic data is also collected continuously.

8.   Regarding Claim 8, Kieval discloses that during the providing step an A-V interval (see col. 17, lines 52-54) comprises a part of the cardiac stimulation sequence. The examiner considers that the main goal of the AV optimization method is to provide an

optimized AV interval to the cardiac pacing regime so an AV interval must be provided to the cardiac stimulation sequence (see col. 4, lines 40-43).

9.   Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

10.   Claims 4 and 9-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval et al. (US Patent 5,626,623) in view of Bornzin (US Patent 5,891,176) in view of Carlson (US Patent 6,026,324).

11.   Regarding Claim 4, see rejection of similarly worded Claim 2 above. As to the activity level measurement means, Kieval discloses an activity sensor 316 optionally coupled to the IPG housing (see col. 10, line 36), thereby coupled to the patient, said activity-level measurement means is derived from a piezoelectric crystal transducer (see col. 10, line 38). Kieval and Bornzin do not disclose that the output signal of said activity-level measurement means is time-synchronized to the hemodynamic monitor means. Carlson discloses that the activity-level output and the hemodynamic monitor output signals in a time-synchronized fashion (see col. 7, lines 10-12). The examiner considers that the activity level measurement means accelerometer 50) must output a

signal at the same time the hemodynamic monitor (accelerometer 16) outputs a signal

to the microprocessor if the level of physical activity is to be a portion of the

hemodynamic signal. It would be obvious to one of ordinary skill in the art at the time of

the invention to synchronize the output of the activity level measurement means to the

hemodynamic monitor means so the activity level can be easily correlated to the

hemodynamic status of the heart and an appropriate AV delay can be determined (see

col. 7, lines 10-34).

12.   Regarding Claim 9, Kieval and Bornzin do not disclose a bi-ventricular device.

The applicant does not disclose any criticality to using a bi-ventricular device over any

other type of stimulation/monitoring device. Furthermore, bi-ventricular devices are well

known and common in the cardiac therapy art. Not only that, an AV device would work

equally as well as a bi-ventricular device. Nevertheless, Carlson teaches that the

method of optimizing a pacing regime could apply to a variety of different devices,

including a bi-ventricular device (see V-V pacing; col. 2, lines 13-16). It would have

been an obvious design choice to one of ordinary skill in the art at the time of the

invention to use a bi-ventricular device as long as a physiological parameter could be

measured along with the level of physical activity in order to provide an appropriate

therapy.

13.   Regarding Claim 10, Kieval, Bornzin, and Carlson all disclose a dual-chamber

pacing mode (see Kieval, Figure 4 and col. 7, lines 54-55; see Bornzin, col. 4, lines 48-

50; see Carlson, col. 3, lines 18-19).

14.   Regarding Claims 11 and 12, Kieval discloses that the hemodynamic data is collected for a preselected period of time (see col. 4, lines 10-13), the preselected period of time being between a few minutes and several days (see col. 12, lines 46-49). The examiner considers that since the initial step of the optimization method includes collecting hemodynamic data (see RVP signals, col. 3, lines 42-44) and the optimization method is performed at pre-determined times of the day for a number of minutes, the collection of hemodynamic data also occurs at pre-determined times of the day for a few minutes.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NATASHA N. PATEL whose telephone number is (571)272-5818. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl H. Layno can be reached on 571-272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the

Patent Application Information Retrieval (PAIR) system. Status information for

published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information

system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Natasha N Patel/   /Kennedy J. Schaetzle/
Examiner, Art Unit 3766   Primary Examiner, Art Unit 3766